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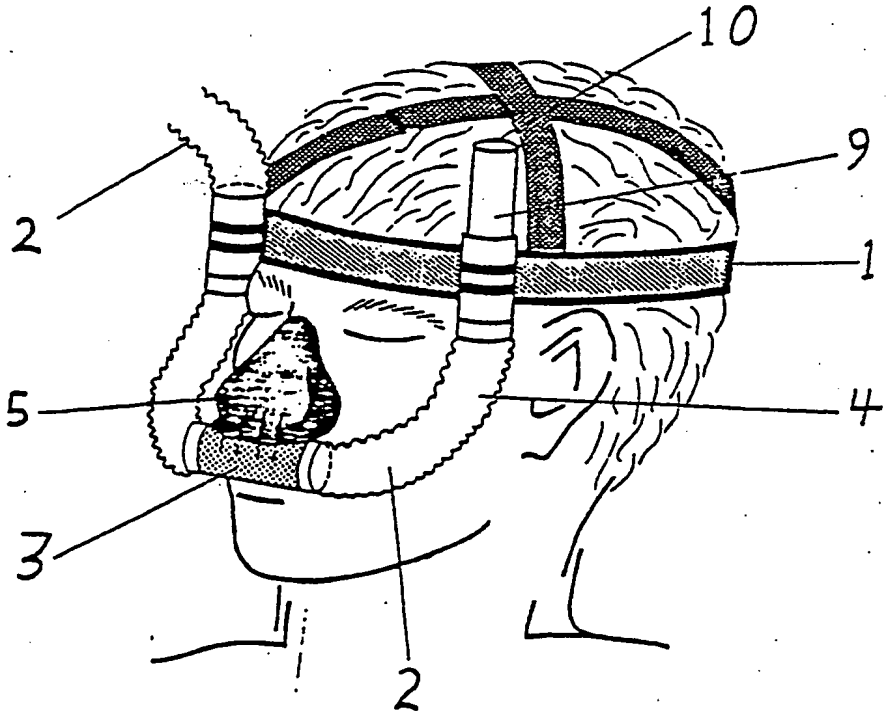
(54) Title: DEVICE FOR TREATING SNORING SICKNESS

(57) Abstract

A device which may be used in the treatment of 'snoring sickness'. An air blower (not shown) supplies high volume air at slightly greater than atmospheric pressure to a flexible tube (2). Such air is communicated via tube (2) through nose piece (3), further flexible tube (2) and a restrictive air outlet device (9). Communicting with nose piece (3) is a face mask (5) adapted to be sealingly attached to a patient's nose and providing communicating between the patient's nostrils and the interior of nose piece (3). By varying the restriction of device (9) the air pressure at the region of nose piece (3), and also the patient's nostrils, can be varied.



"DEVICE FOR TREATING SNORING SICKNESS"

The present invention relates to apparatus which may be used, among other things, for the treatment of Obstructive Sleep Apnoea, more commonly called snoring sickness, which is characterised by occlusion of the upper air passage during sleep. It results from a combination of abnormally restricted upper air passages and the normal loss of muscle tone in the region of the tongue, soft palate and posterior oropharyngeal wall. The condition causes the affected patient to asphyxiate for periods typically of 30 to 120 seconds duration, 200 to 300 times per night. It is a recognised cause of "unexpected" death. In less severe cases it often causes excessive daytime somnolence, heart disorder and brain damage. Some lung diseases are commonly found in association with "snoring" sickness.

The syndrome is a common disorder, particularly in middle aged overweight males, although a person affected may have no awareness of the problem.

BACKGROUND ART

Prior art methods for overcoming the problem include the use of neck collars, respiratory stimulants, loss of weight in cases of obesity and tracheostomys which are left open at night. Only the tracheostomy has been effective in overcoming the problem completely. However in cases where immediate life-threatening complications are not present, the decision as to whether this method should be used or not is obviously difficult.

It is therefore an object of the present invention to provide apparatus which will ameliorate the foregoing disadvantages.

DISCLOSURE OF INVENTION

Accordingly, in one broad form, the invention may be said to consist in apparatus comprising: a length of tubing with at least substantial portions thereof being flexible, having an inlet end for introduction of air under pressure and an outlet end; a nose piece including a cavity shaped for the insertion of a patients nose therein and adapted to be releasably sealed to the patients face in an airtight

manner; at least one opening in an intermediate portion of said tubing forming air communication between said intermediate portion and said cavity; and means to effect resistance to air flow through said outlet end of said tubing to maintain air pressure in the region of said at least one opening at slightly greater than atmospheric air pressure when air is forced therethrough.

BRIEF DESCRIPTION OF DRAWINGS

By way of example only, one preferred form of the invention will now be described with reference to the accompanying drawings in which:

Fig. 1 is a perspective view of a device according to the present invention, absent means for providing air under pressure, in place on a patient;

Fig. 2 is a frontal view of the device of Fig. 1;

Fig. 3 is a detailed view of a portion of the device of Fig. 1;

Fig. 4 is a side view of the portion of a device similar to that of Fig. 3 without the nasal tubes; and

Fig. 5 shows a number of graphs which compare a patients sleep with and without the assistance of the device of Fig. 1.

BEST MODE OF CARRYING OUT THE INVENTION

In Fig. 1 a head band 1, suitably padded, is adapted to fit around the patient's head in a comfortable yet sufficiently firm manner to provide adequate anchorage for the attachment of the components described below. For this purpose commerically available head bands as used with safety hats have been found to be ideal.

A plastic concertina type flexible tube 2 leads from an air blower (not shown) to one side of a rigid tubular nostril piece 3. Some small distance from nostril piece 3 flexible tube 2 is fastened to head band 1. Leading out of the opposite side of nostril piece 3 is another length of flexible tubing which forms the expiratory tube 4. Expiratory tube 4 is also fastened to head band 1 so that when the apparatus is placed on the patients head it is held firmly in place although it offers little discomfort to the

wearer. Flexible tubes 2 and 4 are adapted so that their ends may pass over the respective open ends of nostril piece 3. The flexible tubes are sealingly secured thereto by light weight electrical type clamping bands. These bands may also be used to so secure flexible tubes 2 and 4 to head band 1.

A mouldable nose mask 5 is attached to, or formed as part of, nostril piece 3. Nose mask 5 is shaped so as to fit over most noses and includes a cavity 7 for this purpose. Communicating between cavity 7 and the interior of nostril piece 3 are two openings 6 which are substantially aligned respectively with a patient's nostrils when nose mask 5 is in place. Optional soft nasal tubes 8 can be inserted into openings 6, or formed as part of nostril piece 3, and are adapted to enter the patient's nostrils in certain difficult cases.

The air supply in the preferred form consists of a high volume air pump similar to a vacuum cleaner running in reverse. For this purpose Hitachi (Registered Trade Mark) vortex blower model VB001S has been found to be ideal. The pump may be placed in a sound deadening box.

A variable restriction device 9 in expiratory tube 4 is incorporated in its end. This restriction allows the air pressure at the nostril piece 3 to be adjusted to suit the particular patient using the apparatus. A typical relative pressure for a patient may be 6cm H_2O although a range from 4 to 10 cms H_2O would cover most if not all individuals. The exact location of restriction device 9 is not critical although substantial noise reduction is obtained if it is some distance from the final opening 10.

In use a seal is produced from surgical grade silicon, such as Dow Corning Silastic 382 (Registered Trade Mark), rubber by forming it around the inside of cavity 7 and placing the apparatus in its working position on the patient. The seal and apparatus do not extend down over the mouth. This allows breathing through the mouth while the patient is awake even if the apparatus is in place but not supplying air. This is an important safety aspect.

While in operation the apparatus provides a normal

air mixture to the nostrils of the patient at an adjustable pressure that is slightly above atmospheric pressure. The pressure is initially set at a low level and while the patient is asleep it is gradually increased until occlusions no longer occur. This set pressure should then be adequate for the patient in the future. Although approx. 4 litres of air per second is delivered by the pump much of this leaves the apparatus, via the end restriction, having never been breathed by the patient. The patient inhales normally, the excess pressure merely overcoming the abnormal resistance of the upper air passages and preventing their inward collapse.

Fig. 5 shows a part of a polygraph trace taken from a patient with severe sleep apnea, before and during the application of continuous positive airway pressure (CPAP) via a device of the present invention, in rapid-eye-movement sleep. In the left hand panel (without CPAP), periods of total absence of airflow at the nose are apparent in the nasal pressure trace for up to 45 seconds at a time, despite vigorous movements of ribcage and abdominal wall. Arterial haemoglobin oxygen saturation falls with each apnea as low as 55%. Each apnea is terminaed by arousal from sleep, indicated by bursts of electromyogram activity and movement artifact on electroencephalogram. A few rapid deep breaths follow. Note low voltage, fast electroencephalogram, minimal electromyogram activity, and abundant rapid-eye-movements between arousals. In the right hand panel 9 cm H_2O CPAP via the nosemask completely prevents obstruction, continuous airflow is evidenced on the pressure tracing, arterial oxygen saturation remains normal, and stable uninterrupted sleep is permitted.

While using the above described device exhaling may be slightly affected by the apparatus, and a raised mean lung volume may result, but at the disclosed pressures no danger would exist or adverse side effects be normally encountered.

The present invention has been described in connection with the treatment of obstructive sleep apnea. Other uses of the apparatus of the invention will be obvious

to those skilled in the art and include:

treatment of severe snoring; assistance of breathing during sleep in patients with lung disease;

in intensive care, post-operative and anaesthetic wards to provide continuous positive airway pressure; and

with a conventional respirator to provide assisted positive pressure ventilation in patients with central sleep apnoea (patients who stop breathing during sleep), or sleep hypo-ventilation (patients who dont breath enought during sleep).

The above described apparatus is merely one example of an embodiment of the present invention. Various modifications can be made without departing from the scope of the present invention. For example flexible tubes 2 and 4, nostril piece 3 and nose mask 5 might be moulded in one piece from plastics material.

CLAIMS

1. Apparatus comprising: a length of tubing with at least substantial portions being flexible, having an inlet end for introduction of air under pressure and an outlet end; a nose piece including a cavity shaped for the insertion of a patients nose therein and adapted to be releasably sealed to the patients face in an airtight manner; at least one opening in an intermediate portion of said tubing forming air communication between said intermediate portion and said cavity; and means to effect resistance to air flow through said outlet end of said tubing to maintain air pressure in the region of said at least one opening at slightly greater than atmospheric air pressure when air is forced therethrough.

2. Apparatus as defined in claim 1 wherein said intermediate portion of said tubing is rigid.

3. Apparatus as defined in claim 1 or 2 further comprising a head band adapted to be worn about the patient's head and to which said tubing is secured at points either side of said intermediate portion.

4. Apparatus as defined in any one of the preceding claims wherein surgical grade silicon rubber is used to releasably seal said nose piece to said patient's face.

5. Apparatus as defined in any one of the preceding claims wherein said means to effect resistance to air flow is adjustable so as to provide selectable relative air pressures between 1 cm H_2O and 15 cm H_2O in said region of said at least one opening.

6. Apparatus as defined in claim 5 wherein said relative pressure ranges between 8 to 10 cms H_2O.

7. Apparatus as defined in any one of the preceding claims comprising two only of said openings, each opening including a soft tube for insertion into a respective nostril of a patient.

3 SHEETS SHEET 1

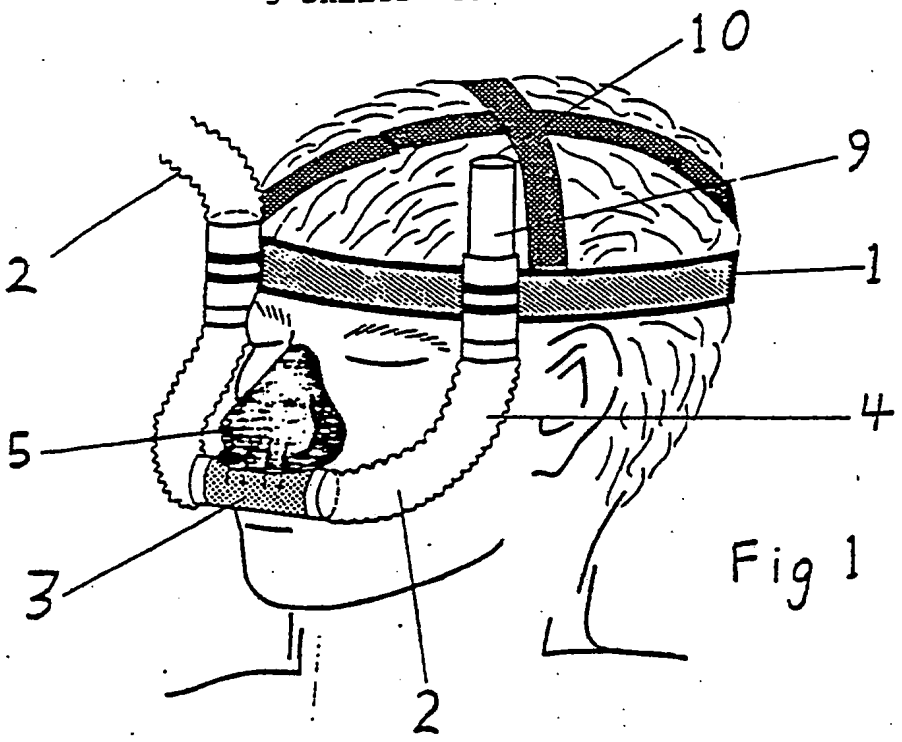


Fig 1

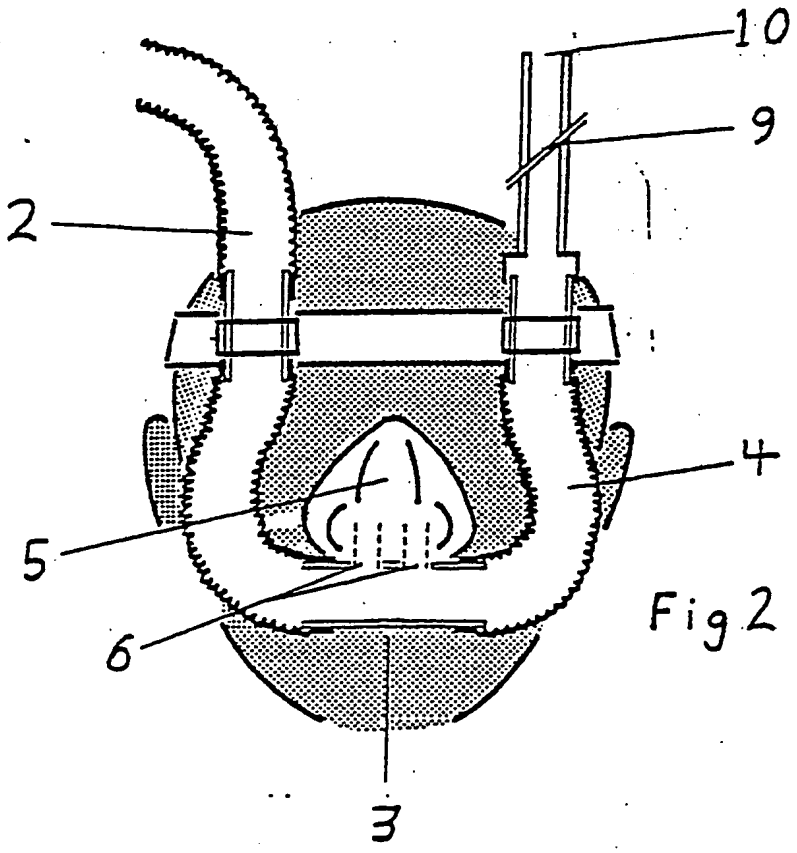


Fig 2

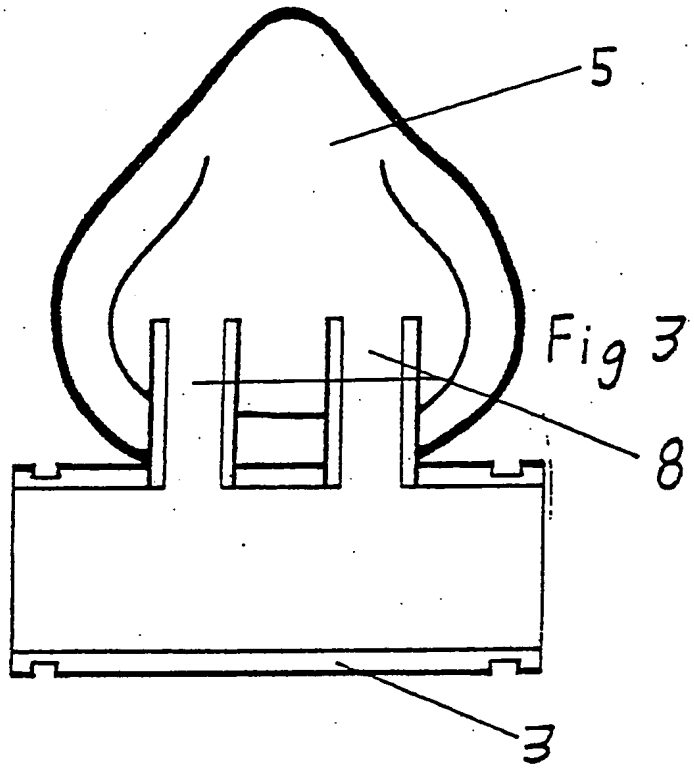


Fig 3

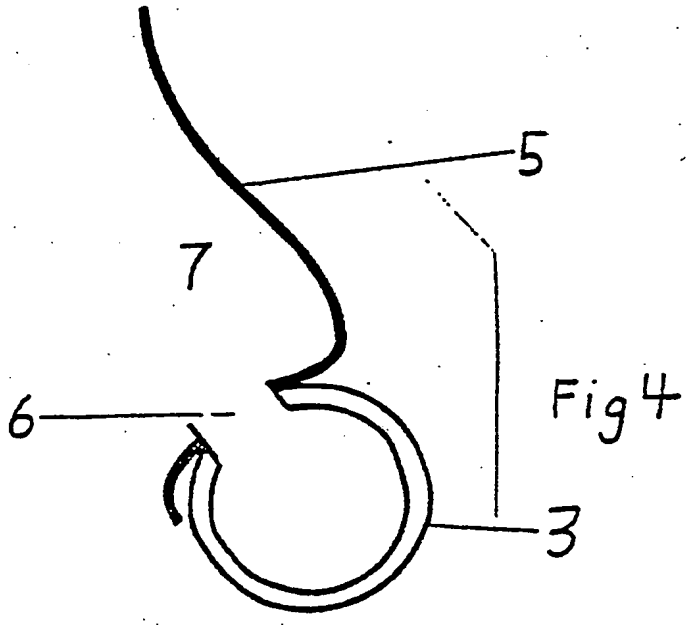


Fig 4

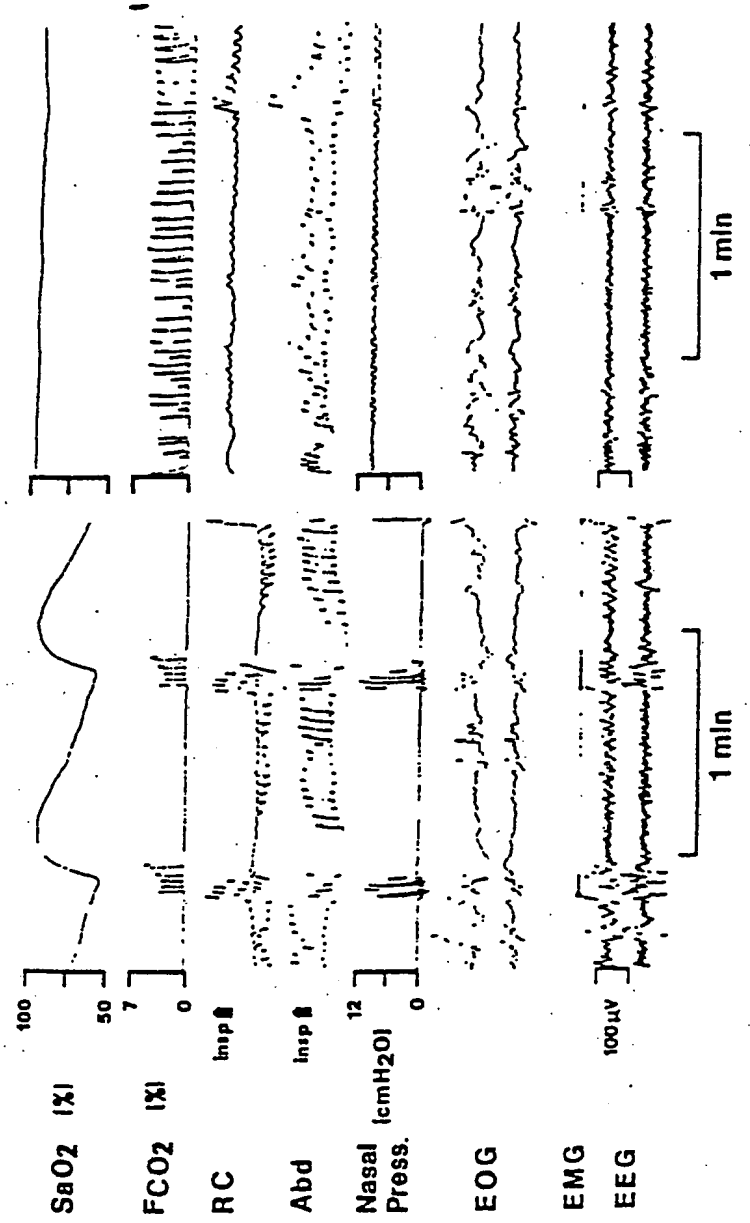


Fig 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU82/00063

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

INT. CL[3] A61F 5/56

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC	A61F 5/56

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

AU: IPC as above; Australian Classification 87.222, 87.224

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
A	US,A, 4304227 (SAMELSON) 8 December 1981 (08.12.81) (& US,A,4169473)	
A	CH,A, 477874 (LEUENBERGER) 31 October 1969 (31.10.69)	
Y	DE,C, 459104 (JANCKE) 26 April 1928 (26.04.28)	
A	DE,C, 849477 (ROSENTHAL) 15 September 1952 (15.09.52)	
A	GB,A, 1551611 (MACVAUGH) 30 August 1979 (30.08.79)	
A	US,A, 2672138 (CARLOCK) 16 March 1954 (16.03.54)	

* Special categories of cited documents: [15]

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [1]	Date of Mailing of this International Search Report [2]
16 June, 1982 (16.06.82)	23 June 1982 (23-06-82)
International Searching Authority [1]	**Signature of Authorized Officer [20]**
Australian Patent Office	D.B. CUPITT

Form PCT/ISA/210 (second sheet) (October 1981)